

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-0632V

BOBBI MOON,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 1, 2024

Leigh A. Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Sarah Black Rifkin, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE¹

On January 12, 2021, Bobbi Moon (“Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the “Vaccine Program”), concerning an influenza (“flu”) vaccine administered in her right arm on October 21, 2019, and her alleged subsequent development of a right-sided shoulder injury related to vaccine administration (“SIRVA”). The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

Respondent opposes Petitioner's claim, arguing that the Act's "severity" requirement cannot be met. After a careful review of the entirety of the parties' submissions, I find there is not preponderant evidence that the alleged injury persisted for at least six months post-vaccination. See Section 11(c)(1)(D)(i). Therefore, her claim is not eligible to proceed within the Vaccine Program, and it must be dismissed.

I. Relevant Procedural History

The original petition alleged that Ms. Moon's right shoulder injury persisted for more than six months post-vaccination. Petition filed Jan. 12, 2021 (ECF No. 1) at ¶ 3; see *also* Declaration of Counsel (ECF No. 1-4) (averring that the petition was filed prior to Respondent's anticipated declassification of SIRVA as a Table injury, and that the supporting medical records would be obtained).³ In August – September 2021, she filed the statutorily-required supporting medical records (as Exs. 1-10) as well as her statutory affidavit, the PAR Questionnaire, and a Statement of Completion (ECF Nos. 8, 10-12, 14). In February 2022, the claim was activated and assigned to SPU (ECF No. 16).

In March 2022, Petitioner filed an Amended Petition which incorporated the medical records (ECF No. 19). She was subsequently directed to file any additional evidence relevant to the statutory severity requirement. Scheduling Order (ECF No. 20). On May 16, 2022, Petitioner and her former husband's unsworn statements on the subject were filed as Exs. 11-12 (ECF No. 21).⁴ On September 2, 2022, Petitioner reported that while she had "residual pain and limitations, she ha[d] not continued with in-office treatment and all updated medical records have been filed at this time." Status Report (ECF No. 25). She anticipated that a demand would include pain and suffering, lost earnings, and medical expenses. *Id.* She conveyed a demand to Respondent on October 17, 2022. Status Report (ECF No. 26).

³ On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule*, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule*, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date*, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule*, 86 Fed. Reg. 21209 (Apr. 22, 2021).

⁴ The statements are neither notarized nor signed under penalty of perjury, as required pursuant to 28 U.S.C.A. § 1746.

On May 18, 2023, Respondent filed his Rule 4(c) Report (ECF No. 30), maintaining that although other elements of a Table claim had been met, severity was not. Rule 4(c) Report at 7. On August 8, 2023, I informed the parties of my review of the record as it stood, and my analysis of the severity showing to date. Petitioner was given an additional 60 days to show cause why her claim should not be dismissed, by way of filing “any additional evidence that is available” and briefing, being sure to acknowledge the critiques of her claim raised to date. Order to Show Cause (ECF No. 32) (hereinafter “Show Cause Order”).⁵

On October 10, 2023, Petitioner argued, based on her briefing of the previously submitted evidence, that “she has preponderantly established the severity of her injury.” Petitioner’s Response to Order to Show Cause (ECF No. 33) at 4 (hereinafter “Show Cause Response”). But Petitioner has not identified any *additional* evidence going towards severity, despite receiving ample opportunity to do so. The matter is now ripe for adjudication.

II. Relevant Evidence

The claim centers on a flu vaccine administered in Petitioner’s right arm at her primary care practice, Mercy Clinic, on October 21, 2019. Ex. 2 at 9. The next medical encounter, two days later with her established chiropractor at the Phipps Clinic, does not reflect any complaints indicative of a SIRVA. Ex. 9 at 76-77.⁶ But ten days post-vaccination, on October 31, 2019, at Mercy Clinic, Petitioner reported that she believed that the flu vaccine had been administered too high in her right upper extremity, and that since that time she had been experiencing right arm pain and swelling. The primary care provider prescribed Mobic and Flexeril. Ex. 2 at 15-16.

On November 15, 2019, Petitioner returned to Mercy Clinic, reporting that her right arm pain had “gotten worse” and was “affecting her sleep,” despite “some relief” with Mobic and Flexeril (which were re-ordered during the encounter). Ex. 3 at 118.

On November 19, 2019, Megan Busch, M.D., at Mercy Clinic recorded that Petitioner could not exercise the left shoulder, lay on that side, and was just in general pain throughout the day. Palpation revealed pain over the anterior rotator cuff and

⁵ This decision generally repeats and incorporates the Show Cause Order’s substantive sections, followed by a review of Petitioner’s Show Cause Response, and some additional concluding analysis.

⁶ Respondent’s Rule 4(c) Report cites to the initially-obtained batch of chiropractic records, at Ex. 9 at 1-67. I have also reviewed the results of Petitioner’s second request for the chiropractic records – which includes the back of each handwritten record, reflecting additional information about the treatment provided by the chiropractor. See Ex. 9 at 68-105.

proximal bicep tendon. Abduction was limited above 145 degrees. Jobe (supraspinatus), Hawkins (impingement), and positive lift off (subscapularis) tests were positive. Dr. Busch prescribed a Medrol dose pack. Ex. 3 at 120-24.

On November 25, 2019, Dr. Busch recorded that Petitioner “responded so well to Medrol dose pack. Said she was pain-free after first day and just started hurting again yesterday after stopping it.” Dr. Busch recommended rest, ice, and prescription indomethacin (a non-steroidal anti-inflammatory medication) as needed. Ex. 3 at 126-29. See *also* Ex. 9 at 54; Ex. 3 at 131-34 (two subsequent medical encounters for other complaints).

On December 6, 2019, Petitioner had an initial consultation with an orthopedist, Dominic Jacobelli, M.D., for her right shoulder complaints. She reported some relief while taking the Medrol dose pack, but added that the pain had returned once she ceased with the medication. NSAIDs had not helped. The pain was “worse with movement and weightbearing to the arm, overhead movements, better when not moving the arm, described as aching and stabbing 8 out of 10 in intensity.” Dr. Jacobelli observed mild tenderness at the proximal biceps tendon, limited range of motion, and the positive signs previously noted. Dr. Jacobelli and Petitioner agreed to continue with conservative treatment plus a referral to physical therapy. “Plan for follow up will be in about 4 to 6 weeks if pain is not improved, next up would likely be a subacromial steroid injection.” Ex. 4 at 31-35.

At the December 12, 2019, physical therapy (“PT”) initial evaluation, Petitioner reported pain currently at 4-5/10, but reaching to 10/10 within the past week. Ex. 5 at 7. The therapist planned formal sessions twice a week for 10 weeks – with an expected end date of March 11, 2020. *Id.* at 9. Long-term goals were to decrease pain to 2/10 at worst; improve range of motion, strength, posture, and body mechanics; return to normal recreational and work activities (noting that Petitioner was a therapist at an elementary school, *id.* at 7); and discharge with a home exercise program (“HEP”). *Id.* at 9-10.

Respondent notes a December 16, 2019, primary care record which contains a “normal musculoskeletal exam” and “no mention of shoulder pain.” Resp. Report at 4, citing Ex. 3 at 135-40. But this encounter was primarily a follow-up on Petitioner’s mental health – during which it was recorded: “the prolonged arm issu[e] has just gotten her down.” Ex. 3 at 135. Another primary care encounter eight days later contains no reference to arm issues, however. *Id.* at 146-48.

Petitioner attended formal PT sessions on December 16 and 27, 2019, and January 2 and 6, 2020. Ex. 5 at 11-22. She endorsed 3/10 pain from her right shoulder injury during a chiropractic appointment on January 7, 2020. Ex. 9 at 80-81. She attended further PT sessions on January 10 and 13, 2020. Ex. 5 at 23-29.

Three months after vaccination, on January 16, 2020, Petitioner attended her eighth and final PT session for her right shoulder. The objective findings included limited external rotation (“to behind head”) and positive Neer’s, Hawkins, Kennedy, empty can, and Yergason’s signs. Ex. 5 at 29, 32. However, the therapist assessed Petitioner as “able to perform full flex/ abd/ IR/ ER ROM R shoulder without pain, minimal pain with R shoulder horiz abd... able to perform duties at work and chores around home without pain.” *Id.* at 31. She had achieved all goals. *Id.* at 32. She was discharged with instructions to continue her HEP. *Id.* at 31-32.

Subsequent records from the primary care provider on January 20th, chiropractor on January 21st, primary care on February 4th, and chiropractor on February 6th and 12th, 2020, do not reflect any right shoulder injury. Ex. 3 at 152-62; Ex. 9 at 82-87.

At a February 19, 2020, chiropractor encounter, Petitioner reported “pain and tightness on right side of neck/ shoulder causing migraine.” She rated more severe pain in her neck (5/10) than in her right shoulder (2/10). Ex. 9 at 88-89.

Subsequent records from the chiropractor on March 11 and 18; primary care on April 6⁷ and May 20; chiropractor on May 21; primary care on June 8; chiropractor on July 9, 10, 15, 20, and 29; and primary care on October 20 and November 4, 2020, do not reflect a right shoulder injury. Ex. 3 at 163-87; Ex. 9 at 90-105. Neither do appointments with a new primary care provider – MANA Family Medicine – on February 3, and March 31, 2021. Ex. 6 at 7-11.

On May 24, 2021 – now approximately *nineteen months* post-vaccination - Petitioner returned to the new primary care provider for an annual wellness exam. The primary care provider recorded:

Pt had rotator cuff torn during flu shot last year, Pt has gone to PT to help with the tear. Requesting refills on rx.

⁷ Additionally on April 6, 2020, the primary care provider marked that Petitioner’s right shoulder injury was “resolved” as of December 16, 2019. Ex. 4 at 10. That was indeed the date of the last primary care encounter addressing the injury – but that date is obviously not dispositive on severity, as she continued PT for the injury until January 16, 2020, Ex. 5 at 29-32.

Would like to discuss her right shoulder injury from flu vaccine. She continues to have limited ROM and pain to shoulder daily. She also reports numbness and tingling several times a week in right arm. She did receive PT for this injury and it is documented in her medical records as ‘vaccine injury.’

Ex. 6 at 4. The primary care provider also recorded: “She continues to have complain of daily pain in right shoulder and numbness that is less often than daily[,] she did complete PT regimen.” *Id.* at 6. An exam revealed “tenderness with palpation to right shoulder – AC joint/deltoid and limited ROM secondary to pain.” *Id.* at 5. However, the primary care provider did not make any related diagnosis (assessing only a vaccine “adverse effect”) or offer any treatment plan or prescriptions (notwithstanding Petitioner’s apparent request for the same), for the shoulder injury. *Id.* Of note, Petitioner also reported “weight loss secondary to anxiety and depression after going through divorce last year...” Ex. 6 at 4.

Neither party has cited any further medical records as relevant to severity. As noted in the procedural history, Petitioner averred that “all updated medical records have been filed at this time.” Status Report filed Sept. 2, 2022 (ECF No. 25).

In a May 2022 unsworn statement, Petitioner states that her shoulder injury persisted for “well over 6 months after the vaccine.” The associated medical appointments were themselves costly, and moreover, required her to miss work – but she has not provided any corroborating evidence of these costs. Moreover, she has not addressed the physical therapy discharge indicating that she had achieved all goals just three months post-vaccination; addressed the numerous medical records not evidencing an ongoing right shoulder injury; or supplemented the record with information about any other circumstances in her life. *See generally* Ex. 11.

In a separate unsworn statement dated April 29, 2022, Jeremy Morris writes that Petitioner’s vaccine injury “last[ed] well over six months and she still has pain to this day because of it.” Mr. Morris states that he saw these symptoms firsthand, and was himself personally impacted by the associated medical bills, because they were married “during the time of her injury.” However, his statement lacks any specificity regarding the date of vaccination, the duration of any particular symptoms, or the dissolution of their relationship. *See generally* Ex. 12. The available evidence reflects that Petitioner and Mr. Morris divorced sometime in 2020. Ex. 6 at 4 (May 24, 2021, medical record stating that Petitioner had “go[ne] through divorce last year”).

III. Statutory Severity Requirement

A. Authority

The petitioner carries the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is “documentation demonstrating severity – generally, that the petitioner⁸ “suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” Section 11(c)(1)(D)(i)⁹; *see also Black v. Sec’y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the “potential petitioner” must not only make a *prima facie* case, but clear a jurisdictional threshold, by “submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case”), *aff’d*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec’y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding a petition requirement “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Medical records must be considered, *see* Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). However, the Federal Circuit has recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

⁸ Or other vaccinee, e.g., a minor or other person who is unable to represent his or her own interests, on behalf of whom the claim is brought.

⁹ Section 11(c)(1)(D) presents two alternative grounds for eligibility to compensation if a petitioner does not meet the six months threshold: (ii) death from the vaccine, and (iii) inpatient hospitalization and surgical intervention. Neither alternative is alleged or implicated in this claim.

It is thus certainly the case that factual matters required to prove elements of a Vaccine Act claim may be established by a *mix* of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

B. Show Cause Analysis

Respondent contends that Petitioner has not established that she suffered from her alleged SIRVA for more than six months post-vaccination, as is required to establish the statutory severity requirement. Report at 7-8, citing Section 11(c)(1)(D)(i).

The Show Cause Order stated that the evidence was indeed inconclusive on this question – and in a way that did not favor Petitioner. As Respondent emphasizes, Petitioner was discharged from PT having met all of her goals just *three* months post-vaccination, in mid-January 2020. One subsequent chiropractic record reflects right shoulder and neck pain, but it includes a higher pain rating for the latter (which would not be properly deemed SIRVA-related), and has no express connection to the vaccine injury. Even if that record is interpreted in Petitioner’s favor, it is from just *four* months post-vaccination. And the records of at least 18 other medical encounters dating over the next 16 months (mid-January 2020 – late May 2021) are silent regarding the existence of an ongoing right shoulder injury, and they reflect Petitioner’s ability to seek medical care for various other concerns, notwithstanding her assertions that medical care was costly and required her to take time off from work. (For the same reason, the Show Cause Order warned that I would not look favorably on any new argument that the COVID-19 Pandemic prevented further medical treatment for her right shoulder, since the record reveals Petitioner obtained treatment in this period).

Overall, the existing evidence suggests that the right shoulder injury was *at best* a lesser concern for which Petitioner deferred any formal treatment for over a year, despite ample opportunity.

After the 16-month gap in any medical record documentation of a right shoulder injury, and despite encounters for various other complaints, in May 2021 Petitioner’s new primary care provider documented objective findings of tenderness to palpation and range of motion limited due to pain. However, this record was obtained in the context of a *new* patient-provider relationship; primarily reflects Petitioner’s own history of the injury and her attribution to the vaccination; and it does not contain any specific diagnosis or treatment plan offered by the provider. While the available evidence does not point to any

clear intervening cause of right shoulder pain at this point, and Petitioner was in her twenties, she had a prior history of pain affecting her *opposite* left shoulder, neck, and hips. See *generally* Ex. 9 (chiropractic records).

The Show Cause Order stated that additional supplementation of the medical record file could resolve the severity question in Petitioner's favor. However, Petitioner had failed up to that point to offer such additional evidence. Her unsworn statement is unpersuasive because it does not acknowledge the PT discharge and the lengthy gap in medical treatment for her shoulder. It lacks specificity about any shoulder symptoms, continued home exercise regimen, or other circumstances in her life.

The additional unsworn statement from Mr. Morris is not helpful either – due to its lack of specificity, and because it is unclear that Mr. Morris would have firsthand recollections of her shoulder condition in 2020, in light of their relationship ending at some point that year. Petitioner had otherwise failed to provide any non-medical evidence to corroborate her allegations.

The Show Cause Order stated that it appeared unlikely (based on the evidence existing at that time) that it could be preponderantly established that Petitioner's right shoulder injury persisted for at least six months after the October 21, 2019, flu vaccine as required to fulfill the statutory severity requirement. I warned that this may be fatal to the claim – although I provided Petitioner one last chance to meet her burden.

C. Petitioner's Show Cause Response and Further Analysis

In maintaining that the existing evidence establishes severity, Petitioner notes that the PT discharge record from mid-January 2020 – three months post-vaccination – included instruction to continue a home exercise program ("HEP"). Show Cause Response at 2. But neither the PT discharge record, nor any other evidence, supports that Petitioner continued the HEP until at least the six-month mark.

Petitioner adds that the subsequent medical records not documenting an ongoing right shoulder injury were focused on unrelated complaints, and often conducted virtually in light of the Pandemic. Show Cause Response at 3. While recognizing that a petitioner is not required to ensure that every subsequent medical encounter documents an ongoing shoulder injury, these encounters do reflect *opportunities* for documentation. In particular, the primary care providers who initially treated the shoulder injury were not obviously restricted by the telemedicine setting. They could have documented any ongoing complaints, then offered at least limited assessment and treatment suggestions. Despite

Petitioner's arguments, the 18 encounters spanning over 16 months not documenting an ongoing right shoulder injury tend to have cumulative weight *against* her allegation.

Petitioner also argues that it is "exceedingly unlikely that [her] symptoms resolved before April 2020 but reemerged, with positive exam findings, in May 2021." Show Cause Response at 4. But the *only* positive evidence of an injury existing beyond six months post-vaccination is the single medical record from May 2021, which reflects Petitioner's history of injury present since the vaccination, and physical exam findings of right shoulder tenderness and painful range of motion. (It also reflects simultaneous right arm numbness and tingling, which are not clearly consistent with her earlier injury and are incompatible with the alleged Table SIRVA, see 42 C.F.R. § 100.3(c)(10)(iii). The numbness and tingling raise the specter of an unrelated injury, potentially related to her preexisting pain in other areas of the body). And notably, the medical provider at that time did not offer any specific diagnosis, treatment plan, or opinion as to whether the current complaint was attributable back to the previous injury documented in October 2019 – January 2020. Thus, this one additional medical record is insufficient to "cure" the substantial treatment gap which otherwise suggests that the post-vaccination right shoulder injury resolved within six months.

Petitioner bears the burden of establishing the statutory severity requirement – and she has received ample opportunity to do so. I cannot conclude that the limited evidence submitted preponderates in her favor.

Conclusion

Petitioner has not established the statutory severity requirement. Therefore, she is ineligible to pursue compensation under the Program. In the absence of a timely-filed motion for either reconsideration or review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this Decision.¹⁰

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.